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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/736,728	03/16/2001	Mahendra S. Rao	UT-0030	7449

7590

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Kathleen A. Tyrrell
Licata & Tyrrell P.C.
66 E. Main Street
Marlton, NJ 08053

EXAMINER

HAYES, ROBERT CLINTON

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 04/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/736,728

Applicant(s)
Rao et al

Examiner
Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 24, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-19 and 49 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-19 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Response to Amendment

1. The amendment filed 1/24/03 has been entered.
2. The rejection of claims 13, 16-19 & 49 under 35 U.S.C. 102(e) as being anticipated by Johe et al. (U.S. Patent 5753506), is withdrawn due to the amendment of the claims and because of Applicants' arguments.
3. The rejection of claims 13-18 & 49 under 35 U.S.C. 102(b) as being anticipated by Gard et al. is withdrawn due to the amendment of the claims.
4. Applicant's arguments filed 1/24/03 have been fully considered but they are not deemed to be persuasive.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. Claims 13-19 & 49 stand rejected under 35 U.S.C. 102(e) as being anticipated by Jat et al. (U.S. Patent 5688692), for the reasons made of record in Paper No: 9 (mailed 10/24/02) and as follows.

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Applicants argue on page 5 of the response that "Jat et al. also fail to teach a method of isolating GRP cells via selection of cells expressing A2B5 antigen". In contrast to Applicants' assertions, column 25 discloses culturing/isolating/obtaining glial cells, as recited in the preamble, in which the isolated glial restricted precursor cells express the A2B5 antigen, as recited (e.g., column 25, lines 3-10); thereby, being selected for expressing A2B5, by definition. In other words, selection of A2B5 expressing cells and obtaining glial cells, as claimed, is taught by Jat. In contrast, no homogenous population of A2B5+ glial restricted precursor cells is required to be obtained in the currently claimed method.

In summary, Jat et al. teach a method of obtaining and propagating a population of mammalian/E18 embryonic rat CNS glial precursor cells that are also differentiated into non-process bearing A2B5-GFAP+ astrocytes and A2B5+ oligodendrocytes in the presence of the factors, PDGF, bFGF (i.e., col. 25; as it relates to claims 13-14, 18-19 & 49), as well as in the presence of the factor, purified cortical astrocyte conditioned medium, which contains 10% fetal calf serum (i.e., col. 23, lines 47-54; as it relates to claims 14 & 15) that inherently also contains thyroid hormone (T3); absent evidence to the contrary (e.g., col. 25; as it relates to claims 18-19). In that Jat et al further disclose a method of differentiation of glial restricted precursors in the presence of bFGF and CNTF, process bearing A2B5+GFAP+ astrocytes are also reasonably produced in their method (i.e., col. 25; as it relates to claims 16-17), as claimed.

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New Grounds of Rejection:

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-19 & 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jat (US Patent 5,688,692) in view of Gard et al.

Jat et al. is as described above.

Gard et al. teach a method of obtaining and propagating rat cerebral progenitor cells (e.g., G_{D3}, O4- and GFAP+ CNS glial progenitor cells) in BDM minimal salt medium containing 0.5% fetal calf serum (FBS) which inherently contains PDGF and FGF; absent evidence to the contrary (i.e., pgs. 597-598; as it relates to claim 49). Gard teach the method of switching these cells upon culturing under differentiating conditions (i.e., in the presence of CNTF) to produce a stellate astrocytic/glial phenotype (i.e., inherently process bearing A2B5+GFAP+; pgs. 598, 2nd

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col.- pg. 600; Fig. 1 & 4 & Table 4; as it relates to claims 13 & 16-18). Differentiation of O4+ glial progenitor/precursor cells into oligodendrocytes is also disclosed by Gard using CNTF (e.g., pg. 600, col. 2- pg. 601; as it relates to claim 18). Differentiation of O4+ glial precursor cells into non-process bearing A2B5-GFAP+ astrocytes in the presence of fetal calf serum (FBS) is further disclosed on pages 601-602 (i.e., as it relates to claims 13-15). Lastly, Gard teach immunopanning as a method of selecting for distinct populations of glial progenitor/precursor cells (e.g., pg. 597). However, Gard et al. do not teach using A2B5 antibodies to isolate glial precursor cells.

It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to initially obtain a pure homogenous population of Jat's glial progenitor cells before differentiating these progenitor cells to various populations of glial cells, as disclosed by both Gard et al. and Jat et al., using Gard's method of immunopanning with Jat's A2B5 antibody, because Gard et al. teach that immunopanning is a technique to "compare, in culture challenges with different... inducing agents, the differentiation potential of ... progenitors isolated directly from early postnatal... forebrain" (e.g., see pg. 597; 1st column). In other words, the differentiation potential of glial precursor cells to different and distinct glial cell populations using specific growth factors, as described by both Jat and Gard, is more accurately determined using homogenous populations of cells initially, by definition.

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8. Claims 13-19 & 49 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: how “selecting cells expressing A2B5 antigen” is accomplished.

It should be noted that should the claims be amended to recite “immunopanning” as disclosed in Example 1 of the specification, the record will need to be clarified on where one can obtain the required antibodies necessary to practice the instant method, in order to avoid any subsequent rejection under 35 U.S.C. 112, first paragraph.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

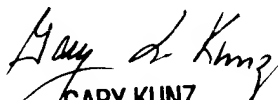
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
April 1, 2003



GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600